Biotech Daily

Tuesday December 5, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMMUTEP (PRIMA) UP 8%; VIRALYTICS DOWN 8%**

*** CSL R&D SPEND UP, NEW ASSETS, TRANSPLANT PORTFOLIO**

*** MARINOVA SEAWEED REDUCES TUMOR, BACKS CHEMO IN MICE**

*** BLUECHIIP WINS $1m US ORDER FOR TRACKING TECHNOLOGY**

*** BOTANIX CANNABIDIOL BTX1503 'POTENT' AGAINST ACNE**

*** FACTOR THERAPEUTICS RECEIVES $3m FEDERAL R&D TAX INCENTIVE**

*** US PATENT FOR NEUREN'S NNZ-2591 FOR AUTISM**

*** PRUDENTIAL (M&G) INCREASES TO 15% OF MESOBLAST**

*** FIL TAKES 10% OF COGSTATE**

*** DIMERIX TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** AVITA APPOINTS DALE SANDER CFO, TIM ROONEY CAO**

*** SPIRO SAKIRIS RESIGNS AS IQ3 DIRECTOR, CONTINUES AS EXECUTIVE**

MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday December 5, 2017 with the ASX200 down 13.8 points to 5,971.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and two were untraded. All three Big Caps fell.

Immutep (formerly Prima) was the best, up 0.2 cents or eight percent to 2.7 cents with 4.2 million shares traded. Neuren climbed 7.6 percent; Actinogen and Medical Developments improved more than four percent; Acrux was up 3.45 percent; Clinuvel and ITL rose more than two percent; Admedus, Mesoblast and Universal Biosensors were up more than one percent; with Opthea and Sirtex up by less than one percent.

Viralytics led the falls, down six cents or 8.4 percent to 65.5 cents with 167,269 shares traded. Benitec lost 7.1 percent; Compumedics, Factor Therapeutics and Telix fell four percent or more; Bionomics, LBT and Nanosonics were down three percent or more; Avita, Impedimed, Oncosil, Optiscan, Opthea and Starpharma shed more than two percent; Pharmaxis, Prana, Pro Medicus and Psivida were down more than one percent; with Airxpanders, Cochlear, CSL and Resmed down by less than one percent.

CSL

CSL says has increased research and development spending five percent to $US645 million for the year to June 30, 2017 and is developing a transplant portfolio.

In its annual research and development briefing, CSL research and development director and chief scientist Prof Andrew Cuthbertson said that part of the increase in spending was to include “a step-up” in the Seqirus division which included the influenza vaccines acquired from Novartis (BD: Oct 27, 2014; Jul 31, 2015).

Prof Cuthbertson said that in the past year, CSL had added sites at Wuhan, China and Pasadena in California and “we have added a franchise area of transplantation [which] will be an area for investment in research and development over time”.

Prof Cuthbertson said that CSL had added gene therapy to its haemophilia assets through the acquisition of Calimmune and its assets for sickle cell anaemia, as well as starting a collaboration with the Cambridge, Massachusetts-based Momenta Pharmaceuticals for first-in-class recombinant multimer proteins, which it expected to have in the clinic as CSL730 in 2018.

CSL head of research Dr Andrew Nash said that CSL730 was expected to be in a pahse I trial by April 2018 and a phase Ib trial in 2019.

Dr Nash said that the Calimmune lenti virus assets was “a great opportunity to treat the disease compared to the symptoms of sickle cell anaemia.

“We think this is a stong platform technology beyond sickle cell anaemia,” Dr Nash said.

Prof Cuthbertson said that CSL paid the Vancouver, British Columbia-based Vitaeris Inc $US15 million upfront for a collaboration on the anti-interleukin-6 monoclonal antibody, formerly known as ALD518 and now called clazakizumab as a therapeutic option for solid organ transplant rejection.

In a media release, CSL said that clazakizumab was a humanized, monoclonal antibody that bound to and inhibited interleukin-6 (IL-6) which was “an important driver of the inflammatory response and [was] known to play a key role in transplant rejection”.

CSL said that it expected to start dosing patients with antibody mediated rejection in kidney transplantation in 2018.

The company said that Vitaeris would retain control of projects to the end of phase III and be entitled to sales-related payments.

CSL said it would pay a royalty to Alder Biopharmaceuticals the innovator of clazakizumab and have an option to acquire Vitaeris, taking board observer and director seats and membership of the scientific advisory board.

“Vitaeris’ transplant rejection program is complementary to CSL’s current development activities in solid organ transplant,” Prof Cuthbertson said.

In the briefing, Prof Cuthbertson said that CSL expected to begin a study of the immune-modulatory effects of alpha 1 anti-trypsin (AAT) for graft versus host disease in 2018.

Prof Cuthbertson said that Janssen had cancelled a study of CSL362 for acute myeloid leukaemia as the drug did not demonstrate an acceptable risk profile and said that the recombinant factor VII CSL689 for haemophilia A program would also be closed.

Prof Cuthbertson said CSL112 would proceed to a 17,000-patient, phase III clinical trial of CSL112 for reduction of early recurrent cardiovascular events in cardiac arrest survivors.

In a media release, CSL said it would be its largest study with about 1,000 sites around the world and would evaluate whether CSL112 could reduce cardiovascular events in high-risk patients during the critical 90-day period following a cardiac arrest.

“We believe CSL112 has the potential to change the current treatment paradigm for heart attack survivors and improve global health outcomes for the millions of people at risk for early recurrent cardiovascular events,” Prof Cuthbertson said.

CSL fell 94 cents or 0.65 percent to $144.37 with 615,883 shares traded.

MARINOVA PTY LTD

Marinova says that fucoidan seaweed extracts reduce tumor growth and improve chemotherapy drug tamoxifen's effectiveness in mice.

The Hobart, Tasmania-based Marinova said it had isolated fucoidans from two types of brown seaweed, Undaria pinnatifida and Fucus vesiculosus, and research undertaken at the Houston-based University of Texas McGovern Medical School showed that the extracts reduced tumour growth in select cancers and significantly improved the effectiveness of tamoxifen.

The company said that fucoidans could be safely used as a complementary cancer therapy alongside traditional chemotherapy.

Marinova said it tested the extracts in six human tumor mouse models, including cervical, breast and ovarian cancers, with the fucoidan extracts orally administered to mice for 30 days and compared to controls and found the extracts "decreased the growth of a human ovarian cancer tumor line by up to 33 percent and a human cervical cancer tumor line by up to 70 percent".

Marinova said the same breast and ovarian cancer models were used to assess fucoidan activity in combination with paclitaxel or tamoxifen and showed that fucoidan "considerably improved the efficacy of tamoxifen towards breast cancer".

"Fucoidan decreased breast cancer tumor growth in this animal model by up to an additional 26 percent when taken alongside tamoxifen," the company said.

Marinova said that in-vitro studies showed that the two fucoidan extracts did not interfere with key metabolic pathways necessary for chemotherapy function and directly inhibited a number of human cancer cell lines, with strong synergistic activity between fucoidan and both paclitaxel and tamoxifen observed, as well as additive activity with topotecan.

Marinova said the studies had been published in the journal Integrative Cancer Therapies, with 'Evaluation Fucoidan Extracts From Undaria pinnatifida and Fucus vesiculosus in Combination With Anticancer Drugs in Human Cancer Orthotopic Mouse Models' at: http://journals.sagepub.com/doi/full/10.1177/1534735417740631 and 'Pre-clinical evaluation of safety of fucoidan from Undaria pinnatifida and Fucus vesiculosus for use by oncology patients' at: http://journals.sagepub.com/doi/abs/10.1177/1534735416680744.

University of Texas Women's Health Integrative Medicine Research Program director Prof Dr Judith Smith led the research project and said it was "the first research program to comprehensively assess the metabolism of fucoidan compounds for possible chemotherapy drug interactions".

"A pharmacokinetic study is now underway at … [the University of Texas] to further assess safety and observe quality of life parameters in human cancer patients," Prof Smith said.

Marinova said that a further study in the research program found that both fucoidan extracts enhanced the immune function of cancer-affected mice, with immune markers immunoglobulin G (IgG) and interleukin 6 (IL-6) both significantly modulated in fucoidan-fed mice, with a 500 percent increase in IgG levels relative to controls after one week.

The company said that IgG was the main type of antibody found in humans and it helped control infections by binding to pathogens such as bacteria and viruses and alerting circulating immune cells, but IgG levels were often suppressed in cancer patients, making them vulnerable to a wide range of infections.

Marinova chief scientist Dr Helen Fitton said that the pre-clinical results confirmed "the potential for fucoidan to help restore functional immunity in cancer patients".

"To have identified a safe, natural compound that has such a significant effect on immunity in an oncology setting is really quite remarkable," Dr Fitton said.

Marinova is a private company.

BLUECHIIP

Bluechiip says it has a $1 million order for its sample tracking technology from US “original equipment manufacturer” partner Labcon North America.
Bluechiip said the order was for the chips, readers, software and services and would be used in a “variety of markets in life sciences including cryogenics, drug screening, cell therapy as well as forensics”.
The company said the sale followed the signing in April of a licence and supply agreement with the San Francisco Bay, California-based Labcon to buy, use, sell, market and promote Bluechiip’s intellectual property, technology and products (BD: Apr 10, 2017).
Bluechiip managing-director Andrew McLellan said it was “our largest order to date and we expect it will be the start of significant growth for the company”.
“The orders are further validation of our partnering strategy, which we put in place two years ago,” Mr McLellan said.
Bluechiip posted revenue for the year to June 30, 2017 of $237,773 and $155,718 for the year to June 30, 2016 and had been attempting to commercialize the technology since listing on the ASX in 2011 (BD: Jun 8, 9, 2011)
Bluechiip climbed 0.9 cents or 24.3 percent to 4.6 cents with 3.5 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says the cannabidiol in BTX1503 has shown “potent anti-bacterial activity against … antibiotic-resistant and non-resistant strains of Propionibacterium acnes”.
Botanix said that in-vitro testing of the BTX1503 synthetic cannabidiol, at an unnamed US laboratory, determined a minimum inhibitory concentration against six clinical isolates of Propionibacterium acnes and four antibiotic-resistant strains of Propionibacterium acnes.
The company said that BTX1503 “showed potent activity against all bacteria tested, with no apparent difference in anti-bacterial activity regardless of whether the bacteria was resistant to antibiotics or not”, the first time that the drug active had shown potent anti-bacterial activity against both types of Propionibacterium acnes.
Botanix said it had filed a new patent application this week.
Botanix executive director Matt Callahan said that the results had ramifications for the company’s clinical development program for acne.
“Combined with our proprietary Permetrex drug delivery technology, BTX1503 effectively delivers the levels of synthetic cannabidiol required to achieve ideal anti-bacterial effects to the target skin layers, where the bacteria reside,” Mr Callahan said.
Botanix said that a factor in acne development was colonization of the hair follicle by Propionibacterium acnes and with the over production of sebum, or oil, on the skin, abnormal proliferation of keratinocytes and inflammation were recognized as the four main factors involved in the development of acne.
The company said the study was the first that “confirms a compound that can target all four pathogenic factors”.
Botanix scientific advisory board member and the head of the High Point, North Carolina-based Dermatology Consulting Service Dr Zoe Diana Draelos said that the “multi-pathogenic ingredient combined with an established safety profile makes BTX1503 a very exciting acne treatment candidate”.
Botanix said that BTX1503 was currently in an up to 20-patient phase Ib Australian study due to complete enrolment this year, with data available shortly thereafter.
The company said that each patient would receive BTX1503 treatment over four weeks and would be assessed for safety and treatment effects (BD: Aug 21, 2017).
Botanix was up 0.7 cents or 12.1 percent to 6.5 cents with 24.7 million shares traded.

FACTOR THERAPEUTICS

Factor Therapeutics says it has received $3,107,592 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Factor said that the Federal R&D Tax Incentive refund related to expenditure in the year to June 30, 2017 for its phase IIb study of VF001 for venous leg ulcers and investment in other assets in its portfolio including its ocular program and collaboration with Monash University.
Factor Therapeutics fell 0.2 cents or four percent to 4.8 cents.

NEUREN PHARMACEUTICALS

Neuren says the US Patent and Trademark Office has allowed a patent for NNZ-2591 for treating an autism spectrum disorder or neuro-developmental disorder.
Neuren said the patent, entitled 'Neuroprotective Bicyclic Compounds and Methods for Their Use in Treating Autism Spectrum Disorders And Neurodevelopmental Disorders', related to a method for treating an autism spectrum disorder or neurodevelopmental disorder using cyclic glycyl-2-allyl proline, or NNZ-2591, and would provide intellectual property protection until July 2034.
The company said that similar applications were pending in Europe and Japan.
Neuren said the new patent would supplement composition of matter patents in the US, Europe and Japan which provided coverage until 2024, with the potential to extend the expiry to 2029.
The company said that NNZ-2591 was a synthetic analog of the neurotrophic peptide cyclic glycine proline which occurred naturally in the brain.
Neuren said that NNZ-2591 had demonstrated efficacy in pre-clinical models of Parkinson's disease, stroke, traumatic brain injury, peripheral neuropathy, Fragile X syndrome, memory impairment and multiple sclerosis.
The company said that cyclic glycine proline had been shown to regulate the binding of insulin-like growth factor 1 (IGF-1) to IGF binding protein 3 in the brain.
Neuren said that an abnormally high amount of IGF binding protein 3 was a feature of Rett syndrome.
The company said that validation of a recently granted patent relating to the use of lead molecule trofinetide to treat autism spectrum disorders had been completed in all the member states of the European Patent Organisation, providing cover until 2032 (BD: May 31, 2017).
Neuren executive chairman Dr Richard Treagus said the new patent would "further strengthen the robust commercial exclusivity that has been put in place for both trofinetide and NNZ-2591, through a combination of composition of matter patents, method patents and orphan drug exclusivity periods".
Neuren was up 19 cents or 7.6 percent to $2.69.

MESOBLAST

Prudential PLC says with its subsidiaries it has increased its holding in Mesoblast from equivalent to 65,452,353 shares (14.19%) to 69,390,670 (14.73%).
The London-based Prudential said that M&G Investment Management and Eastspring Investment were wholly-owned subsidiaries.
The company said it bought and sold shares between September 18 and November 30, 2017, with the single largest purchase 273,937 shares for $392,420 or $1.43 a share.
Mesoblast was up 1.5 cents or 1.15 percent to $1.32.

COGSTATE

FIL Limited says it has increased its substantial shareholding in Cogstate from 9,344,356 shares (8.26%) to 11,426,018 shares (10.00%).
The Hong Kong-based FIL said it bought the 2,081,662 shares on May 22 and November 30, 2017 at prices ranging from 85 to 87 cents.
Cogstate was up two cents or 2.2 percent to 94 cents.

DIMERIX

Dimerix has requested a voluntary suspension to follow the trading halt requested last week pending an announcement of “a proposed capital raising” (BD: Dec 1, 2017).
Dimerix last traded at 15.5 cents.

AVITA MEDICAL

Avita says it has appointed Dale Sander as its chief financial officer, replacing Tim Rooney, who becomes chief administrative officer, effective from today.
Avita said that Mr Sander would be responsible for overseeing finance and investor relations functions and aligning them with the company’s commercialization strategy.
The company said that Mr Rooney would be responsible for operations and supply chain management, human resources, and information technology.
Avita said that both executives would be based in Valencia, California.
Avita chief executive officer Dr Mike Perry said that Mr Sander had more than 20 years of experience, including as chief financial officer of four medical device and pharmaceutical companies as well as 11 years of leading public companies as a chief financial officer.
Mr Perry said that Mr Sander had experience in public and private equity offerings, including multiple initial public offers in the US and Europe, as well as “a strong track record of managing investor relations in these markets as well as in Asia”.
Avita fell 0.2 cents or 2.9 percent to 6.8 cents with 1.9 million shares traded.

IQ3 CORP

IQ3 says that director Spiro Sakiris has resigned from the board effective from December 4, 2017 but will continue with the company as an executive.
IQ3 said that Mr Sakiris would focus on compliance and international projects as well as infrastructure work in the US and Asia-Pacific.
IQ3 was untraded at 19 cents.